K132541

510(k) Summary
Trinity ELE Device

Updated: October 1st, 2013

CONTACT INFORMATION

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DEVICE NAME

Trade Name: Trinity ELE
Common Name: Facial Stimulation Device
Classification Name: Transcutaneous Electrical Nerve Stimulator (21 CFR 882.5890)
Product Code: NFO

PREDICATE DEVICE

The Carol Cole Company is claiming substantial equivalence with its own device, the NuFACE® Trinity device, cleared as the NuFACE® Plus under 510(k) K103472. This Abbreviated 510(k) submission is a new design based on the manufacturer's cleared device. Both devices are for transcutaneous electrical nerve stimulation for cosmetic use.

INDICATIONS FOR USE/INTENDED USE

The Trinity ELE is intended for facial stimulation and is indicated for over-the-counter cosmetic use. (21 CFR 801 Subpart C).

The anatomical site for application of the Trinity ELE is the face.

TECHNOLOGICAL CHARACTERISTICS

The Trinity ELE is a non-invasive at home, over-the-counter facial stimulation device. The dual spheres of the Trinity ELE are designed for optimal contact with smaller surface areas of the face. The Trinity ELE is extremely responsive as it delivers soft wave micro-current in the millionths of an ampere and has the ability to increase facial contour and firm the skin and muscles. The Trinity ELE continually alternates between the positive and negative probes, and allows the user to adjust settings from approximately 53 to 192 microamps for a personalized comfort level.

The Trinity ELE measures 2.8" W x 6.2" L x 1.3" D. Its outer case is injection molded of thermoplastic resin. The device comes with a Charging Cradle, which measures 3.1" W x 4.0" L x 3.3" D, to charge the internal batteries of the main body when not in use. The Charging Cradle is powered by DC power from a pre-approved wall adapter Power Supply provided with the device. All charging circuitry is contained within the main body unit itself.

An ascending sequence of beeps informs the customer the Trinity ELE is ready for

use. When the user turns off the device, a descending tone is emitted.

To promote proper use, a single audio beep informs the user to relocate the device to treat a new location on the skin. The user can also adjust output by pressing the + or – intensity buttons to increase or decrease the micro-current output.

COMPLIANCE DATA

The Trinity ELE was tested and found to conform with the FDA's performance Standards set forth in 21 CFR §898.

The Trinity ELE was also tested and found to be in compliance with IEC 60601-1-2 for radiated and power line conducted emissions. The Trinity ELE was evaluated and found to be in compliance with IEC 60601-1 for Electrical Safety.

SUBSTANTIAL EQUIVALENCE

The Trinity ELE has the same intended use and indications for use as the predicate device. The device also has similar technological characteristics. During design and development, a Risk Analysis of the device was used to identify potential Hazards that could occur in use of the device, or in the event of Failure Modes of device components. The Risk Analysis was used to identify risk reduction measures which have been incorporated in the device design and labeling.

The determination of substantial equivalence for the Trinity ELE is based on an assessment of non-clinical performance. This assessment included a comparison of the output of the Trinity ELE to that of the predicate. The output performance testing included:

1. Waveform type (e.g., pulsed monophasic, biphasic)
2. Waveform Shape (e.g., rectangular, spike, rectified sinusoidal)
3. Maximum Output Voltage
4. Maximum Output Current
5. Output Tolerance
6. Pulse Width
7. Output Frequency
8. Maximum Phase Charge
9. Maximum Current Density
10. Maximum Power Density (using smallest electrode conductive surface area)
11. Burst Mode (i.e., pulse trains)
    a. Pulses per burst
    b. Pulses per second
    c. Burst duration
    d. Duty Cycle
12. ON Time
13. OFF Time

The results are provided in Section 3 (Output Specifications) below. As shown in the Substantial Equivalence Comparison Table:

1. Waveform type is identical to the predicate
2. Waveform Shape is identical to the predicate
3. Maximum Output Voltage is less than the predicate due to maintaining the Maximum Current Density is identical to the predicate
4. Maximum Output Current is less than the predicate due to maintaining the

Maximum Current Density identical to the predicate
5. Output Tolerance is identical to the predicate
6. Pulse Width is identical to the predicate
7. Output Frequency is identical to the predicate
8. Maximum Phase Charge is less than the predicate due to maintaining the Maximum Current Density is identical to the predicate
9. Maximum Current Density is identical to the predicate
10. Maximum Power Density is less than the predicate due to maintaining the Maximum Current Density is identical to the predicate
11. Burst Mode (i.e., pulse trains)
    a. Pulses per burst is identical to the predicate
    b. Pulses per second is identical to the predicate
    c. Burst duration is identical to the predicate
    d. Duty Cycle is identical to the predicate
12. ON Time is identical to the predicate
13. OFF Time is identical to the predicate

The dual spheres of the Trinity ELE are smaller in size than the predicate to allow optimal contact with smaller areas of the face. To maintain the Maximum Current Density with these smaller spheres identical to the predicate with larger spheres, the output current was reduced corresponding to the reduced contact area. As a result, the Maximum Output Voltage, Maximum Output Current, Maximum Phase Charge, and Maximum Power Density were correspondingly reduced.

The results support a determination of substantial equivalence in that the smaller spheres of the Trinity ELE treat a smaller area of the face with the same Current Density as the predicate.

Section 1: Device Descriptions

Trinity ELE and NuFACE® Trinity Device Comparison Table

Section 1: Device Descriptions	Trinity ELE Device New Device	NuFACE® Trinity Predicate Device
1. 510(k) Number	K131251	K103472
2. Regulation Number	21 C.F.R. § 882.5890	21 C.F.R. § 882.5890
3. Regulation Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
4. Regulatory Class	Class II	Class II
5. Product Code	NFO	NFO
6. Intended Use	Stimulate the face; skin toning	Stimulate the face; skin toning
7. Indications for Use	Over-the-Counter Cosmetic Use	Over-the-Counter Cosmetic Use
8. Technological Characteristics	The Trinity ELE is an over-the-counter facial stimulation device. The chrome plated dual spheres of the Trinity ELE are designed to gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face. The Trinity ELE probes are designed for optimal contact with smaller surface areas of the face. The Trinity ELE microcurrent continually alternates between the positive and negative probes, and allows the user to adjust settings from approximately 53 to 192 microamps for a personalized comfort level. The Trinity ELE device measures 2.8" W x 6.2" L x 1.3" D. Its outer case is injection molded of thermoplastic resin. The device comes with a Charging Cradle, which measures 3.1" W x 4.0" L x 3.3" D, to charge the internal batteries of the main body when not in use. The Charging Cradle is powered by DC power from a pre-approved wall adapter Power Supply provided with the device. All charging circuitry is contained within the main body unit itself. To turn the device on, the on/off button is pressed. An ascending sequence of beeps and one to five blue LED lights illuminate indicating the unit is ready for use. Users then follow the instructions for use. The Trinity ELE requires the use of a conductive gel or medium. The user can also adjust output level by pressing the + or – intensity buttons to increase or decrease the microcurrent output. To promote proper use and feedback to the user, the Trinity ELE beeps to cue the user to relocate the device after approximately 5 seconds of treatment. When the user turns off the device, a descending tone is emitted.	The NuFACE® Trinity is an over-the-counter facial toning device. The chrome plated dual spheres of the NuFACE® Trinity are designed to gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face. The NuFACE® Trinity probes are designed for optimal contact with the face. The NuFACE® Trinity microcurrent continually alternates between the positive and negative probes, and allows the user to adjust settings from approximately 0 to 400 microamps for a personalized comfort level. The NuFACE® Trinity device measures 2.8" W x 5.1" L x 1.3" D Its outer case is injection molded thermoplastic resin. The device comes with a Charging Cradle, which measures 3.1" W x 4.0" L x 3.3" D, to charge the internal batteries of the main body when not in use. The Charging Cradle is powered by DC power from a pre-approved wall adapter Power Supply provided with the device. All charging circuitry is contained within the main body unit itself. To turn the device on, the on/off button is pressed. An ascending sequence of beeps and one to five blue LED lights illuminate indicating the unit is ready for use. Users then follow the instructions for use. The NuFACE® Trinity device requires the use of a conductive gel or medium. The user can also adjust output level by pressing the + or – intensity buttons to increase or decrease the microcurrent output. To promote proper use and feedback to the user, the NuFACE® Trinity beeps to cue the user to relocate the device after approximately 5 seconds of treatment. When the user turns off the device, a descending tone is emitted.

Section 2: Basic Unit Characteristics

Trinity ELE and NuFACE® Trinity Device Substantial Equivalence Comparison Table

Section 2: Basic Unit Characteristics	Trinity ELE Device New Device	NuFACE® Trinity Predicate Device
1. 510(k) Number	K131251	K103472
2. Device Name, Model	Trinity ELE Device	NuFACE® Trinity
3. Manufacturer	Carol Cole Company (CCC)	Carol Cole Company (CCC)
4. Power Source(s)		
a. Method of Line Current Isolation	4 rechargeable AA NiMH batteries	4 rechargeable AA NiMH batteries
b. Patient Leakage Current		
1. Normal condition	N/A - Battery Operated	N/A - Battery Operated
2. Single fault condition	N/A - Battery Operated	N/A - Battery Operated
5. Number of Output Modules	1	1
6. Number of Output Channels	1	1
a. Synchronous or Alternating	N/A - 1 Output Channel	N/A - 1 Output Channel
b. Method of Channel Isolation	N/A - 1 Output Channel	N/A - 1 Output Channel
7. Regulated Current or Regulated Voltage?	Both	Both
8. Software/Firmware/ Microprocessor Control?	Yes	Yes
9. Automatic Overload Trip?	Not required due to circuit design	Not required due to circuit design
10. Automatic No-Load Trip?	Yes	Yes
11. Automatic Shut Off?	Yes	Yes
12. Patient Override Control?	Yes	Yes
13. Indicator Display		
a. On/Off Status?	Yes	Yes
b. Low Battery?	Yes	Yes
c. Voltage/Current Level?	Yes	Yes
14. Timer Range (minutes)	Yes (21 minutes)	Yes (21 minutes)
15. Compliance with Voluntary Standards?	EN 60601-1 EN 60601-1-2	EN 60601-1 EN 60601-1-2
16. Compliance with 21 CFR 898?	Yes	Yes
17. Weight	9 oz without charging base	9 oz without charging base
18. Dimensions of device(inch) [W x L x D]	2.8" W x 6.2" L x 1.3" D	2.8" W x 5.1" L x 1.3" D
19: Dimensions of charging Unit (inch) [W x L x D]	3.1" W x 4.0" L x 3.3" D	3.1" W x 4.0" L x 3.3" D
19. Housing Materials and Construction	Thermo Plastic	Thermo Plastic

Section 3: Output Specifications

Trinity ELE and NuFACE® Trinity Device Substantial Equivalence Comparison Table

Section 3: Output Specifications	Trinity ELE Device New Device	NuFACE® Trinity Predicate Device
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed Biphasic	Pulsed Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Modulated Square	Modulated Square
Maximum Output Voltage (specify units)	96 mV @ 500 Ω	137 mV @ 500 Ω
	384 mV @ 2 kΩ	769 mV @ 2 kΩ
	1.92 V @ 10 kΩ	3.82 V @ 10 kΩ
Maximum Output Current (specify units)	193 µA @ 500 Ω	274 µA @ 500 Ω
	1193 µA @ 2 kΩ	387 µA @ 2 kΩ
	192 µA @ 10 kΩ	383 µA @ 10 kΩ
Output Tolerance	+/- 5%	+/- 2%
Pulse Width (specify units)	60 ms	60 ms
Frequency (Hz)	8.33 Hz	8.33 Hz
For interferential modes only		
Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency
For multiphasic waveforms only		
Symmetrical phases?	Not Multiphasic	Not Multiphasic
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Not Determined	Not Determined
Net Charge (µC per pulse)	N/A - Battery Operated	N/A - Battery Operated
Maximum Phase Charge (µC)	11.5 µC @ 500 Ω	23.9 µC @ 500 Ω
Maximum Current Density (mA/cm²)	0.739 mA/cm² @ 500 Ω	0.518 mA/cm² @ 500 Ω
Maximum Power Density (µW/cm²) (using smallest electrode conductive surface area)	1420 µW/cm² @ 500 Ω	1423 µW/cm² @ 500 Ω
Burst Mode (i.e., pulse trains)		
a. Pulses per burst	20	20
b. Pulses per second	8.3	8.3
c. Burst duration (seconds)	2.4	2.4
d. Duty Cycle [Line (b) x Line (c)] (on time per burst)	20	20
ON Time (seconds)	Constant	Constant
OFF Time (seconds)	None	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 1, 2013

Carol Cole Company
c/o Ms. Rand Daoud
Compliance Specialist
1325 Sycamore Ave, Suite A
Vista, CA 92081

Re: K131251
Trade/Device Name: Trinity ELE
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: August 28, 2013
Received: August 29, 2013

Dear Ms. Daoud:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131251

Device Name: Trinity ELE

Indications For Use:

The Trinity ELE is intended for facial stimulation and is indicated for over-the-counter cosmetic use (21 CFR 807 Subpart C).

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___x___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S